Claim Rejections-35 U.S.C. §103

Cosman

Claims 23-27, 29, 33-39, 44, 48, 49, and 70-91 stand rejected under 35 U.S.C. §103 as being obvious over U.S. Patent No. 6,530,922 issued to Cosman et al. ("Cosman"). Applicant respectfully traverses this rejection, since Cosman does not disclose, teach, or suggest the combination of elements required by these claims.

As the Examiner has pointed out, Cosman fails to disclose "providing a first probe in a first aperture to create a first lesion, then removing the probe and placing it in a different aperture to create a second lesion," as required by independent claim 23, or the "sequential operation of the probes," as required by independent claim 35. However, the Examiner concludes that Cosman specifically teaches that it was known to provide for the creation of individual lesions and to provide sequential heating with various probes, and that it would have therefore been obvious to modify the Cosman method to serially or sequentially activate a single probe or multiple probes to create multiple lesions in tumor tissue.

While Applicant does not disagree that it was known to serially or sequentially activate a single probe or multiple probes to create multiple lesions (see background of present application), Applicant does disagree that one of ordinary skill in the art would have been motivated to modify the Cosman method in the manner suggested by the Examiner. A reading of Cosman, as a whole, would suggest to one of ordinary skill in the art that ablation energy should only be simultaneously delivered to electrodes that have been guided through a stereotactic guide to operate as a single larger electrode. It is established principle that "a prior art reference must be considered in its

entirety, i.e., as a whole, including portions that would lead away from the claimed invention." (See M.P.E.P. §2141.02).

Besides emphasizing that the ablation energy should be simultaneously (as opposed to serially or sequentially) delivered to the cluster of electrodes, Cosman repeatedly states that simultaneous delivery of ablation energy to the cluster of electrodes allows the electrode cluster to become a larger, coherent electrode, so that the heating effect is similar to that accomplished by a single electrode (see col. 3, line 63 to col. 4, line 5; col. 6, lines 50-57; col. 7, lines 23-26; col. 8, lines 32-40). That is, the method disclosed in Cosman was merely meant to replace previous ablation methods that utilizes a single larger ablation probe—not to create compound lesions. Thus, when Cosman mentioned the prior art step of sequentially delivering ablation energy to electrodes, Cosman was merely comparing it to the prior art step of simultaneously delivering ablation energy to electrodes, and emphasizing that the latter step is to be implemented in the Cosman method—i.e., ablation energy is to be simultaneously delivered to electrodes that have just been guided through a stereotactic guide. Cosman was not disclosing an alternative method, but rather was teaching away from the sequential delivery of ablation energy to the guided electrodes.

As such, Cosman does not suggest to one of ordinary skill in the art that the stereotactic device disclosed in Cosman be used to generate compound lesions—but quite the opposite—a single larger lesion. In contrast, Applicant has invented a method for accurately and efficiently creating compound lesions, so that the physicians need not estimate the initial location, and even the depth, of the ablation probe(s), thereby minimizing or obviating the need to reposition the ablation probe(s)—especially when addressing difficulty related to reduced ultrasonic image visualization caused by the

echogenic cloud produced by previous ablations. Cosman does not suggest modifying the disclosed method for this purpose or any purpose.

It should also be noted that independent claim 23 requires guiding an ablation probe within different apertures in the alignment device, and delivering ablation energy to the same ablation probe to create a compound lesion. Nowhere does Cosman disclose, teach, or suggest that the same ablation probe can be guided through different apertures in the stereotactic device to create a compound lesion. Not only does Cosman fail to suggest the sequential delivery of ablation energy to a cluster of guided electrodes, the entire disclosure of Cosman revolves around the formation of electrode arrays by guiding multiple electrodes through an alignment device, thereby seemingly excluding, or at the least teaching away from, any methodology wherein the same ablation probe is guided through different apertures in an alignment device. The title of the Cosman patent, i.e., Cluster Ablation Electrode Systems, evidences this.

Thus, Applicant submits that independent claims 23 and 35, as well as the claims depending therefrom (claims 24-27, 29, 33, 34, 36-39, 44, 48, 49, and 70-91) are not obvious over Cosman, and as such, respectfully request withdrawal of the rejections of these claims.

Among other claims, claims 70, 71, 74, and 75 provide additional patentable features not disclosed, taught, or suggested in Cosman. In particular, claims 70 and 74 require the ablation probe(s) to include a cannula with at least one electrode deployable within the first and second regions. Claims 71 and 75 further require the electrode(s) to include a plurality of tissue-piercing electrode tines configured to be deployed radially outward. Significantly, not only does Cosman fail to suggest the use of cannulae with deployable electrodes, such a modification would defeat the objective set forth in Cosman.

It is an established principle that if a proposed modification would render the prior art device or method being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. (See M.P.E.P. §2143.01). See In re Gordon, 733 F.2d 900 (Fed. Cir. 1984). In the present case, Cosman describes several problems associated within the use of cannulae with deployable electrodes and attempts to solve these problems with the disclosed method. In particular, these problems include hemorrhaging caused by the relatively large diameter cannula and multiple passes of the electrodes, as well as the irregularities and undulations in the resulting lesion shape. Cosman states:

> A severe hazard of multiple extrusion of side-outlet electrodes is that it produces hemorrhaging by the multiple passes of the side outlet electrodes near the central cannula. Also, at the periphery of such side-emitting electrode lesions, irregularities and undulations in lesion shape and inhomogeneities in temperature around the side-emitted electrode tips produce hot and cold spots over the lesion volume. These may cause focal boiling and charring of tissue with unpredictable and dangerous consequences. For example, consider a large tumor of about 3 to 4 cm diameter in the liver. In such an example, there is a further risk that such undulations and variations in the shape of the periphery of the heat ablation zone would cause portions of the cancerous tumor to be missed by the heat ablation, which of course, would result in continued tumor growth and progression of cancer. Further, a single central cannula, which has one or many side-emitting radiofrequency electrode tips has a diameter, which increases with the number of radiofrequency tips that emerge from it. When the diameter reaches 3 to 4 mm for such a central cannula, there is the disadvantage of increased risk of hemorrhage and/or great pain or discomfort to the patient during insertion of the large central cannula into the tissue. (col. 3, lines 7-29)

To address these problems, Cosman emphasizes the insertion of very small needle electrodes through the apertures of a stereotactic guide, rather than using a large cannula with a plurality of deployable needle electrodes, and simultaneously applying RF energy to the electrodes, stating:

> Contrary to existing electrode configurations and techniques, which propose inserting one large electrode into body tissue, thereby often causing severe hemorrhage, the present system of coherent cluster electrodes inserts into body tissue, multiple independent rigid electrode shafts of the cluster, each of appropriate small diameter, which reduces the risk of hemorrhage. The problem of irregular lesion ablation zones

> and inhomogeneities of ablation regions associated with prior side-emitting electrodes is also avoided by the coherent cluster electrodes of the present invention. (col. 4, lines 12-22).
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> Yet another advantage of the coherent cluster electrode system of the present invention is that in accordance with one embodiment it enables all its electrodes to be inserted in unison and in a known geometric relationship to one another. In one embodiment, each electrode may be configured with a small shaft with a pointed, self-penetrating tip. Accordingly, the chance of a hemorrhage occurring from a multiple cluster of such smaller electrodes is less likely than with a single electrode of larger diameter. Even if the cluster of electrodes is not inserted in a precisely parallel fashion, the effect of their coherence in making a larger lesion volume is still effective. (col. 4, line 58 to col. 5, line 2).
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> An advantage of a multiplicity of coherent smaller electrodes versus insertion of a single large electrode is that the smaller electrodes will produce less chance of hemorrhage. The arrangement of their geometry may also be tailored to the clinical application. Insertion of several small gauge electrodes is less painful, uncomfortable, and risk-inducing than insertion of one large, equivalent radiofrequency electrode. For example, insertion of a cluster of several 18 gauge or 1.25 mm diameter pointed radiofrequency electrodes into the liver produces very low risk of hemorrhage and low discomfort. Insertion of an equivalent, but much larger single electrode, which may have a diameter of, for example, 0.25" or 6.4 mm, would have a higher risk of hemorrhage and would be very uncomfortable for the patient if the electrode were inserted percutaneously. (col. 9, line 57 to col. 10, line 4).

Thus, it can be appreciated from a reading of the entire disclosure that there is no suggestion in Cosman, and in fact a teaching against, guiding a cannula with deployable electrodes through the apertures of the sterotactic device. Thus, an additional reason as to why claims 70, 71, 74, and 75 are patentable over Cosman.

Cosman and Morris

Claims 28 and 40-43 stand rejected under 35 U.S.C. §103 as being obvious over Cosman in view of U.S. Patent Publication No. 2002/0120261 to Morris et al. ("Morris"). Applicant respectfully traverses this rejection, since neither of Cosman nor Morris disclose, teach, or suggest the combination of elements required by these claims. In particular, as discussed above, Cosman

does not disclose, teach, or suggest the activation of the same ablation probe guided through different apertures of an alignment device or the sequential activation of ablation probes that have been guided through respective apertures of an alignment device, and Morris does not supplement this failed teaching. As such, Applicant respectfully requests withdrawal of the rejections of claims 28 and 40-43.

Conclusion

Based on the foregoing, it is believed that all claims are allowable, and thus, a Notice of Allowance is respectfully requested. If the Examiner has any questions or comments regarding this amendment, the Examiner is respectfully requested to contact the undersigned at (714) 830-0600.

Respectfully submitted,

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